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lee & hayes pllc, intellectual property law

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Fax Cover Sheet

Date: 1/23/2007

To: **David C. Thomas, Patent Examiner** 571-272-3320

From: **Mark Farrell (LEE & HAYES, pllc)**

Re: App No. 10 / 731,419

Phone: (509) 324-9256

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Number of Pages including cover sheet: 3

Hi Examiner Thomas!

Can we schedule a phone call / Examiner interview?

Thanks,

-Mark

PTOL-413A (09-04)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Applicant Initiated Interview Request Form

Application No.: 10/731,419 First Named Applicant: BASSEM A. BESSANI
Examiner: DAVID C THOMAS Art Unit: 1637 Status of Application: A/F

Tentative Participants:
(1) DAVID THOMAS - EXAMINER (2) MARK FARRELL - APPLICANT'S COUNSEL
(3)_____ (4)_____

Proposed Date of Interview: before Jan 27, 07? **Proposed Time:**_____ **(AM/PM)**

Type of Interview Requested:
(1) [X] Telephonic (2) [ ] Personal (3) [ ] Video Conference

Exhibit To Be Shown or Demonstrated: [X] YES [ ] NO
If yes, provide brief description: See next page.

Issues To Be Discussed

Issues (Rej., Obj., etc)	Claims/ Fig. #s	Prior Art	Discussed	Agreed	Not Agreed
(1) Rej § 102	1	CHENCHIK, GORDON	[ ]	[ ]	[ ]
(2)_____	_____	_____	[ ]	[ ]	[ ]
(3)_____	_____	_____	[ ]	[ ]	[ ]
(4)_____	_____	_____	[ ]	[ ]	[ ]

[ ] Continuation Sheet Attached

Brief Description of Arguments to be Presented:
See next page. Chenchik ref. is not in same field. Applicants know the inventors of the GORDON ref. (Joan GORDON; Clark RUSSELL) these people do not think the GORDON ref reads on Applicants claims. The molecular bio community is about to publish Applicants technique - after the GORDON inventors just asked Applicants for a summary paragraph for publication - pretty good evidence that GORDON does not anticipate.

An interview was conducted on the above-identified application on _____

NOTE: This form should be completed by applicant and submitted to the examiner in advance of the interview (see MPEP § 713.01).

This application will not be delayed from issue because of applicant's failure to submit a written record of this interview. Therefore, applicant is advised to file a statement of the substance of this interview (37 CFR 1.133(b)) as soon as possible.

_____ Applicant/Applicant's Representative Signature

_____ Examiner/SPE Signature

MARK C. FARRELL
Typed/Printed Name of Applicant or Representative

45,988
Registration Number, if applicable

RE: EXAMINER INTERVIEW # 10/731,419

Gordon Response:
Claim 1 of our methodology does not require the use of vectors or any double stranded constructs. Our invention employs a mix of single stranded oligonucleotides that are able to be exponentially amplified directly (starting from single stranded fragments) using one single primer pair to amplify every fragment in the control mixture which may or may not be included in the control mix. By varying the concentration of each reference oligonucleotide or primer pair, we are able to modulate amplification of all of the differing control oligonucleotides that when used in a test method will produce a standardized mix of PCR amplicons for all mutations of interest. This is beyond the scope of the Gordon patent. The Gordon patent refers to producing double stranded DNA products and primarily deals with utilizing primers specific to each cassette fragment to generate an appropriate level of PCR amplicon to be used for cloning methods to gencrate each cassette. While both methods employ the use of primers and PCR amplification, the design and application of these methods are used in a manner to produce fundamentally different results at completely different stages. The purpose of the Gordon methodology, in reference to introduced PCR primer sites, is to produce a pure (cassette specific) collection of double stranded fragments for each single cassette that will eventually be used for digestion and subsequent ligation 5' to 3' into a construct containing a vector. The added primer sites introduce restriction sites for subsequent cloning experiments and this is a common practice and not novel. The constructs carrying one or more of these "cassettes" in a vector comprise a finished control product as cxplained in the Gordon patent. The artificial primer sites that were introduced for generating "cassettes" arc not used in ways beyond those illustrated above or in the downstream testing or additional amplification of these cassettes by the test methods for which these controls are designed. Thc Gordon methodology generates double stranded fragments that are then ligated into a vector to produce a single control molecule carrying multiple mutations "in series". Our methodology produces small fragments that are single stranded and amplify exponentially by either an internal or external primer pair based on the design of the artificial tags introduced at the 5' and 3' end of each fragment. Our control carries multiple control molecules "in parallel" which is not anticipated by Gordon.

Hi Examiner Thomas,

The GORDON reference inventors regard applicants' subject matter as novel, (Applicants and Gordon inventors, of course, know each other.) The molecular bio community regards Applicants' subject matter as novel -- and about to be published too.

— Mark Farrell
45,988